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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,008

12/03/2003

Robert W. Stadler

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,008

Applicant(s)

STADLER ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-21,24-41 and 44-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4-21,24-41 and 44-57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed August 3, 2006 have been fully considered but they are not persuasive for reasons stated below.

The Applicant states that the invention is "directed to accumulating a difference between an adaptive baseline trend and one of a most recent measured impedance and a short term trend". The Applicant further argues "Combs teaches the determination of edema based on the simple difference between the long term averages, not the accumulation of this difference over time".

However, Combs does in fact teach a accumulated difference over time, as seen in col. 9, lines 48-59, "It will now be apparent that not only a single data point (LTA-STA) can be used to determine the extent and progression of the edema. A chart or history of the impedance (LTA-STA) versus time could be used to determine the effectiveness of drug therapy by including an index circuit or memory circuit with comparative values in the device. A determination of how severe the disease is by how quickly the edema progresses (i.e. if the change was seen over the course of two weeks, versus one day) becomes a measure that has value to the patient and physician and can be a stored value kept in a memory circuit by a device made in keeping with this invention". Therefore, the difference is an accumulated difference over time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4-7, 9-11, 13-15, 19-21, 24-27, 29-31, 33-35, 39-40, and 57 stand rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al (U.S. 5957861) as previously made of record and stated below.

With reference to claims 1-3, 21-23, and 57, Combs et al. teach an implantable apparatus for impedance measurement that has at least two electrically isolated electrodes that determine the impedance of the body between the two preferred electrodes (see column 3, lines 16-25). Combs et al. further teach an apparatus and method for determining long term and short term average values and for determining when to sample impedance measurements and trigger means for determining diagnostically significant events based on long term and short term average values (see column 3, lines 51-57). The apparatus and method is used to determine pulmonary edema or local edema based upon comparison of long term average impedance values compared to the short term average values, and additionally, the long term averages can be derived from measurements taken over a number of days, while the short term average represents the number of hours. If the device is expected to detect very short term rises in impedance, a short term value should be measured in minutes and long term in less than a week (see column 9, lines 64-67 and column 10, lines 1-20). While

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not stated explicitly that one of a most recent measured impedance is used to generate the impedance change, Combs et al. do teach that "this type of setup would accommodate the rapid rise that sometimes hospitalizes patients after eating a salty meal, for example, allowing a warning to be generated or direct intervention started without the need for hospitalization" (see column 10, lines 21-25). This infers that a most recent measured impedance is used to generate the impedance change.

Referring to claims 4 and 24, Combs et al. teach that the difference is taken between the average signal value of the long term average storage circuit verses the value in the short term average (see column 9, lines 1-4). While not stated explicitly, if the difference is taken, and the short term values correspond to the long term values, the difference would inherently be set to zero.

With reference to claims 5-7, 9-11, 25-27, and 29-31, Combs et al. teach the baseline impedance over an extended period that is based on the respiration cycle (see column 7, lines 9-31). Combs et al. further teach that the sampling period can then be adjusted based on the desires of the patient (see column 10, lines 5-20).

Regarding claims 13-14 and 33-34, Combs et al. teach that the event detection criteria circuit operates by determining if the sign is positive and the value is greater than a programmable percentage of the long term average. If the criteria are met, the circuit will cause a detection signal to be generated. A memory circuit may be provided to store short term and long term average values.

Regarding claims 15 and 35, Combs et al. teach the method and apparatus described above, but do not explicitly teach that the impedance is generated between

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12 pm and 5 pm. Combs et al. do teach that the impedance can be measured and generated at preprogrammed times such as at 5-15 minute intervals or even for every cardiac cycle or every hour (see column 8, lines 5-9). Combs does not state expressly that the impedance is generated between 12 pm and 5pm, however, if the impedance is generated continuously at such preprogrammed intervals, the impedance would be generated between 12 pm and 5 pm.

With regards to claims 19 and 39, Combs et al. further teach when the value is greater than a programmable percentage of the long term average, the detection signal will be generated (see column 9, lines 38-47). With regards to claims 20 and 40, the device taught by Combs et al. determines the long term average by detecting impedances over a number of days (see column 10, lines 14-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 8, 12, 16-18, 28, 32, 36-38, 41, 44-56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al for reasons previously made of record and restated below.

With reference to claim 41-47, 49-50, and 55-56, Combs et al. teach the apparatus described above, and further teach a circuit that has a stimulation circuit and a measurement circuit connected to the electrodes (see column 8, lines 49-55). Combs et al. do not teach a microprocessor explicitly, but do teach a physical event detection criteria circuit that provides an output signal to an output circuit (column 9, lines 4-5). The circuit further operates by determining if the sign on the impedance change is positive and the value is greater than a programmable percentage of the long term average and will cause a detection signal to be generated if it meets the criteria (see column 9, lines 38-43). The circuit is not called a microprocessor, however, the circuit disclosed by Combs et al. performs the same function as the microprocessor disclosed by the Applicant in essentially the same way with the same results.

In addition, it is well known in the art to use a microprocessor in an implantable device to perform functions and make determinations such as determining averages and trending data. Microprocessors are a popular choice for said functions in implantable medical devices because they are small, inexpensive, and are capable of performing functions desired within implantable medical devices. Therefore, it would

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have been obvious to one skilled in the art at the time the invention was disclosed to combine the device taught by Combs et al. with a microprocessor because they are small, inexpensive, and can perform various functions.

With regards to claims 8, 12, 16-18, 28, 32, 36-38, 48, and 52-54, Combs et al. disclose the claimed invention but do not disclose expressly the measurement of impedance four times, updating the short term value using a weighted sum, setting the trends using downdrifts and updrifts, and setting the downdrift to a value of 0.055 ohms and setting the updrift to 0.18 ohms, respectively. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the impedance measurement device as taught by Combs et al. with the measurement of impedance four times, updating the short term value using a weighted sum, setting the trends using downdrifts and updrifts, and setting the downdrift to a value of 0.055 ohms and setting the updrift to 0.18 ohms, respectively because the Applicant has not disclosed that measuring impedance four times, updating the short term value using a weighted sum, setting the trends using downdrifts and updrifts, and setting the downdrift to a value of 0.055 ohms and setting the updrift to 0.18 ohms, respectively provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the sampling rate chosen by the programmer (see column 10, lines 5-8), the averages of the long term and short term impedances, updating the trends by sampling the impedances and averaging them as taught by Combs et al, because it detects impedance measurements to be used for calculating the average short term and long

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term measured impedances and provides an accurate updated impedance average and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Combs et al. Therefore, it would have been an obvious matter of design choice to modify Combs et al. to obtain the invention as specified in claims 8, 12, 16-18, 28, 32, 36-38, 48, and 52-54.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

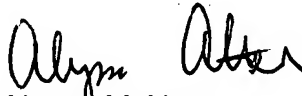
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762

GEORGE R. EVANISKO
PRIMARY EXAMINER
5/14/7